Attachment B2

Kinetic Surgical LLC

k061292

Statarius™ Endoscope Holder Summary

JUL - 3 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All information included in this document is accurate and complete to the best of KSLLC's knowledge.

Applicant:	Kinetic Surgical LLC 2157 Vista La Nisa Carlsbad, CA 92009
Contact Person:	Jim Caputo President
Date of Summary:	05/05/06
Device Name:	Statarius™
Common Name:	Endoscope Holder
Regulatory Class:	Class II
Predicate Device:	Armand Endoscope Holder (K5050051)
Intended Use:	The Statarius™ is intended for use by surgeons for holding rigid and flexible endoscopes with diameters from 5-12mm during diagnostic and therapeutic surgical procedures.
Device Description:	The Statarius™ is a manually operated, mechanical surgical device. It is primarily composed of stainless steel and anodized aluminum. The instrument provides for the one handed control for the positioning/repositioning of an endoscope during surgical procedures. The Statarius™ eliminates the need for the surgeon or assistant to continuously hold an endoscope during surgical procedures.

Substantial Equivalence: The Statarius™ is substantially equivalent in application and function to the Armand Endoscope Holder.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2006

Kinetic Surgical, LLC
c/o Mr. Jim Caputo
President
2157 Vista La Nisa
Carlsbad, California 92009

Re: K061292
Trade/Device Name: Statarius™ Endoscope Holder
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: June 20, 2006
Received: June 23, 2006

Dear Mr. Caputo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment B1

K061292

Indications for Use

510(k) Number: K061292

Device Name: Statarius™ Endoscope Holder

Indications For Use:

The Statarius™ is intended for use by surgeons for holding rigid and flexible endoscopes with diameters from 5-12mm during diagnostic and therapeutic surgical procedures.

Prescription Use X (Per 21 CFR 801Subpart D) AND/OR Over-The-Counter ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061292